

# INEOS Oligomers

January 2009

## Indopol® Regulatory Bulletin

### FOREWORD

This bulletin summarizes regulatory information for Indopol® Polybutenes including chemical inventory status and clearances for applications such as cosmetics/personal care use, food contact use, agricultural use, and others.

### FOOD CONTACT APPLICATIONS

#### Europe:

Indopol grades H-100, H-300, H-1200, H-1500, H-1900, H2100, H-6000, and H-18000 are Isobutylene-butene copolymers covered under the PM/REF: 62280 and the CAS N°: 009044-17-1 by the Annex II of Directive 2008/39/EC amending Annex III of Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food.

Indopol grades L-2, L-3, L-6, L-14, L-50, H-7, H-8, H-15, H-25, H-35, H40, and H-50 are not covered by above Directives; thus not suitable as additives to plastics to be used for food contact applications.

Components of Indopol® Polybutenes are listed in Council of Europe Resolution AP(2004)1, version 2 of 29-01-2008, Technical Document N° 1 version 2 of 10-10-2007, List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs.

#### U.S.A:

Indopol® Polybutenes meet the composition requirements of the following paragraphs of Title 21 of the Code of Federal Regulations of the U.S. Food and Drug Administration, and other applicable regulations. Clearance of specific grades has to be determined on the basis of limitations or specifications on use mentioned below.

§177.1430 Isobutylene-butene copolymers



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**Table 1 - Specifications:**

Isobutylene-butene copolymer	Molecular weight (range)	Viscosity (range)	Maximum bromine value
1. Used as release agents in petroleum wax complying with § 178.3710 of this chapter.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
2. Used as plasticizers in polyethylene or polypropylene complying with § 177.1520 and in polystyrene complying with § 177.1640.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
3. Used as components of nonfood articles complying with §§ 175.300, 176.170, 176.210, 177.2260(d)(2), 177.2800, and 178.3570 (provided that addition to food does not exceed 10 parts per million), or § 176.180 of this chapter.	300 to 5,000 ...	40 to 20,000 seconds Saybolt at 200 °F.	40
4. Used as production aids in the manufacture of expanded (foamed) polystyrene articles complying with § 177.1640 of this chapter.	150 to 5,000 ...	Less than 20,000 seconds Saybolt at 200 °F.	90
5. Used in release coatings on backings or linings for pressure-sensitive adhesive labels complying with § 175.125 of this chapter	150 to 5,000 ...	Less than 20,000 seconds Saybolt at 200 °F.	90

§175.105 Components of adhesives

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## Lubricants with Incidental Food Contact

### U.S. Department of Agriculture and National Sanitation Foundation (USDA/NSF) Registrations

The U.S. Department of Agriculture administered an authorization program for Proprietary Substances and Nonfood Compounds until February 1998. In January 2000, the National Sanitation Foundation revived the USDA program as a voluntary registration program, incorporating previous USDA authorizations and new NSF registrations. Further information and a listing of authorized substances can be found at NSF's website: [www.nsf.org/usda/](http://www.nsf.org/usda/).

**Table 2 - Summary of Indopol® Polybutenes Authorized by USDA and/or registered by NSF as H1-Lubricants with Incidental Food Contact**

Indopol L-14	Indopol H-35	Indopol H-1900
Indopol L-50	Indopol H-50	Indopol H-2100
Indopol H-7	Indopol H-100	Indopol H-6000
Indopol H-8	Indopol H-300	Indopol H-18000
Indopol H-15	Indopol H-1200	
Indopol H-25	Indopol H-1500	

### South America:

- Mercosur/GMC/RES. N0 32/07, Reglamento tecnico mercosur sobre "Lista positive de aditivos para materiales plasticos destinados a la elaboracion de envases y equipamientos en contacto con alimentos" (Derogation de las Res GMC N° 95/94 y 50/01.
- Brazil : Components of Indopol® Polybutenes are listed in Resolução N° 105 de 19 de maio de 1999.

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## COSMETICS/PERSONAL CARE PRODUCTS

Indopol® Polybutenes are used in various cosmetic and personal care applications.

The Personal Care Products Council INCI name for Ineos Indopol Polybutenes is 'Polybutene'.

## TOYS

Indopol® Polybutenes meet the relevant requirements of Directive 2005/84/EC. Indopol grades H-100, H-300, H-1200, H-1500, H-1900, H2100, H-6000, and H-18000 are suitable for toy applications. As Indopol grades L-2, L-3, L-6, L-14, L-50, H-7, H-8, H-15, H-25, H-35, H40, and H-50 are not covered by above mentioned European food contact Directive 2002/72/EC and its amendments, we do not recommend to use them as additives to plastics to be used for toy applications.

## AGRICULTURAL USE – FIFRA

Indopol® Polybutene is a List 4B Inert Ingredient. It is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as exempt from the requirements of a tolerance for residues when used as an inert ingredient in pesticide formulations.

**Table 3 - Summary of FIFRA Polybutene Tolerance Citations**

Citation	Ingredient	Applied to	Limits	Uses
40 CFR 180.960	Butene, Homopolymer			
40 CFR 180.920	Polybutene – as isobutylene-butene copolymer	growing crops only	soil application only	Binder

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## CHEMICAL INVENTORY INFORMATION

Many countries have chemical control legislation in place including a comprehensive list of existing chemicals which may be marketed, manufactured or imported. These lists are known as chemical inventories. Indopol® Polybutenes have been evaluated to determine compliance with these chemical inventories.

**Table 4 - Summary of Chemical Inventory Status**

Country	Indopol L-2 and L-3	Indopol L-6 through H-18000
USA (TSCA)	In Compliance	Listed
EC (EINECS)	In Compliance	In Compliance
Canada (DSL)	In Compliance	Listed
Japan (ENCS)	In Compliance	Listed
Australia (AICS)	In Compliance	Listed
Korea (ECL)	In Compliance	Listed
Philippines (PICCS)	In Compliance	Listed
China (IECS)	In Compliance	Listed

## MANUFACTURING ORIGIN AND PURITY

Indopol® Polybutenes are additives and solvent free products.

## “N” SUBSTANCES

None of the raw materials used in the manufacture of Indopol® Polybutenes are classified as dangerous to the environment (carcinogenic, mutagenic or toxic for the reproduction substance) with the symbol “N” in Annex 1 of the Directive 67/548/EEC (adapted to technical progress for the 28th time by Directive 2001/59/EC).

## CALIFORNIA PROPOSITION 65

Indopol® Polybutenes do not contain any substances listed under California Proposition 65.



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## **HEAVY METALS, WEEE, WASTE PACKAGING, CONEG**

Indopol® Polybutenes meet the relevant requirements of the following Directives or Regulations:

- 2003/11/EC
- 2002/96/EC (WEEE)

Cadmium, lead, mercury, and hexavalent chromium or compounds of these metals are not used raw materials in the manufacture of Indopol® Polybutenes. Therefore, the incidental total level of these metals in these products is far below the limit of 100 ppm as set up in the two following legislations.

- 94/62/EC (Packaging Waste Directive)
- USA CONEG Regulation

## **END-OF LIFE VEHICLES**

Indopol® polybutenes meet the relevant requirements of Directive 2000/53/EC.

## **RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (RoHS)**

Lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE), listed in Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) are not used as raw materials in the manufacture of Indopol® Polybutenes.

## **PHTHALATES**

Phthalates are not used as raw materials in the manufacture of Indopol® Polybutenes.

## **DIOXINS AND FURANS**

Dioxins and furans are not used as raw materials in the manufacture of Indopol® Polybutenes. These substances will not be generated and released during the manufacture and processing of these grades.

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## OZONE LAYER-DEPLETING AGENTS

Chlorofluorocarbons (CFC's) and substances related to ozone depleting substances (as defined by the MONTREAL PROTOCOL and listed as class I & II substances by the US Clean Air Act) are not used as raw materials in the manufacture of Indopol® Polybutenes.

## ABSENCE OF SUBSTANCES AND CHEMICALS

None of the following substances are used as raw materials in the manufacture of Indopol® polybutenes:

- Allergens (as defined in Directive 2000/13/EC, as amended)
- Aromatic amines and colorants
- Azodicarbonamide or semi-carbazide compounds
- Asbestos
- Brominated flame retardants
- Bisphenol-A
- Di(ethylhexyl) adipate
- Epoxidised Soya Bean Oil (ESBO)
- Formaldehyde (formol)
- Latexes
- Nonylphenol and its derivatives
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds
- Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
- Vinyl chloride monomer and its polymers or copolymers

## BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) – TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE)

Indopol® Polybutenes are produced entirely by a petrochemical process, with all feedstocks coming from oil refinery streams. No vegetable material, animal fats, oils, milk products or other animal products are used as components of, or in the manufacture of these products.

## GENETICALLY MODIFIED ORGANISM (GMO)

No genetically modified substances are used as raw materials in the manufacture of Indopol® Polybutenes

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## MATERIAL SAFETY DATA SHEETS / SAFETY DATA SHEETS

Material Safety Data Sheets (MSDS /SDS) are available for all Indopol® Polybutenes, and describe the health, safety and environmental characteristics of these products as well as advice on handling precautions and emergency procedures.

MSDS should be consulted and fully understood before handling, storage or use of Indopol® Polybutenes. To request a copy of a specific Indopol® Polybutenes grade Material Safety Data Sheet, phone 1-866-363-2454 Toll Free – (North America), +32 (0)67 875 980 (Europe), +86 21 6103 5970 (Asia), or send an e-mail to [oligomersmsds@ineos.com](mailto:oligomersmsds@ineos.com).

## INEOS CARES

This bulletin has been prepared by INEOS' Product Stewardship Department. Product Stewardship responsibly manages HSE issues and activities related to the supply and marketing of products, including HSE, R&D, marketing and manufacturing functions, thus embracing every stage of the petrochemical product lifecycle.

For more information, please call 1-866-363-2454 Toll Free in North America.

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